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POREX
SURGICAL PRODUCTS GROUP

K091807

JUN 28 2010

510(k) SUMMARY

Date of Summary: June 21, 2010

Manufacturer and Submitter:

Porex Surgical, Inc.
15 Dart Road
Newnan, GA 30265
Tel: (678) 479-1610
Fax: (678) 479-4495

Contact: Stephanie Fullard
E-mail: stephanie.fullard@porex.com

Trade Name: Porex Fixation System for Maxillofacial Surgery

Common Name: Plates and Screws

Class: II, 21 CFR 872.4760 – Plate, Fixation, Bone
II, 21 CFR 872.4880 – Screw, Fixation, Intraosseous

Product Code: JEY
Subsequent Product Code: DZL

Substantially equivalent to:

1) Synthes (USA)
Synthes Craniofacial Plates
K021642

2) Synthes (USA)
SMF Ti Alloy Bone Screws
K963546

3) Stryker Leibenger
Universal CMF System
K022185

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Device Description:

The Porex Fixation System is a plate and screw system to be used in maxillofacial surgery and is provided in various configurations. The components that comprise the systems are composed of unalloyed titanium plates, titanium alloy bone screws and surgical stainless steel instruments for the installation of the screws. The plates are manufactured of grade 4 titanium and adhere to the American Society of Testing Materials (A.S.T.M.) F67 standard. The screws are manufactured of 6-4 ELI titanium that meets the A.S.T.M F136 standard. The screws are provided in 1.5mm diameter and 4mm length. The rescue screws are green color annodized and provided in 1.8mm diameter and 4mm length. The Porex Fixation Systems are sterilized by ethylene oxide sterilization.

Indications for Use:

The Porex Fixation System for maxillofacial surgery is intended for rigid fixation in the repair of maxillofacial fractures and in maxillofacial reconstruction. The Porex Fixation System for maxillofacial surgery is intended for single use.

Technological Characteristics:

The Porex Fixation System has the same intended use and is manufactured from substantially the same materials as the predicate devices. The technological characteristics of the design are substantially equivalent to the predicate devices and any slight differences raise no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Stephanie Fullard, RAC
Regulatory Affairs Manager
Porex Surgical, Incorporated
15 Dart Road
Newman, Georgia 30265

JUN 28 2010

Re: K091807
Trade/Device Name: Porex Fixation System For Maxillofacial Surgery
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: June 21, 2010
Received: June 23, 2010

Dear Ms. Fullard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091807

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Indications for Use

510(k) Number (if known): **K091807**

Device Name: Porex Fixation System For Maxillofacial Surgery

Indications for Use: The Porex Fixation System for maxillofacial surgery is intended for rigid fixation in the repair of maxillofacial fractures and in maxillofacial reconstruction. The Porex Fixation System For Maxillofacial Surgery is intended for single use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091807